GASTROSTOMY DEVICE PACKAGE AND METHOD OF ASSEMBLY

BACKGROUND OF THE INVENTION

This invention relates generally to a gastrostomy feeding device and specifically, to a novel and improved gastrostomy feeding device for deploying an internal bolster into a patient's stomach where a constraining member that encases the internal bolster takes the form of either a dissolvable capsule that is deployed using a ripcord or a sacrificial tape wrapping.

There are many medical applications in which a device or substance must be contained or constrained prior to placement in the body. Methods commonly used to insert non-balloon type entral feeding devices result in excessive patient discomfort.

It is known that devices are available for supplying food and/or medication to a patient within the stomach. For example, US Patent No. 4,666,433 discloses such a gastrostomy feeding device that is inserted through a stoma and into the patient's stomach. The '433 device is secured in place by an inflatable balloon or mushroom tip within the stomach, and by an adjustable ring on the abdominal wall.

US Patent No. 5,941,855, which is included herein in its entirety by reference, discloses a gastrostomy device having a tubular portion, first and second fingers, a rod member and a suture member. The rod member and suture member cooperate to releasably retain the fingers

in an installation configuration for insertion through a patient's stomach. Following insertion, the rod member and suture member release the fingers to permit the fingers to move to a deployed configuration. In the installation configuration, the fingers are generally in line with an axis of the tubular portion while, in the deployed configuration, the fingers are generally transverse to the tubular portion axis.

It is also known that emplacement of a gastrostomy tube is simplified by compressing the enlarged end into a capsule or binding of a material that dissolves in the body. US Patent No. 4,393,873 discloses a gastrostomy tube packaged for insertion using a gelatin capsule technique. The head is compressed and wrapped or bound in a soluble suture thread or other web or thread made of a material which is soluble in the stomach.

Certain medical devices called stents are well known and have a variety of forms. US Patent 5,234,457 discloses a stent which is maintained in a collapsed condition by a dissolvable material. When the stent is placed in a vessel and bounded by a vessel wall, the material changes from a solid to a liquid to permit the stent to expand into the vessel wall.

Although it is common in the art to use the medical devices described above, the present invention improves upon them by providing a technique wherein a dissolvable member and a ripcord are combined onto a gastrostomy feeding device. The ease and comfort of the patient improves greatly using the present invention and the ripcord gives the

caregiver an immediate and positive indication that the internal bolster has been released into the patient's body unlike the prior art devices.

SUMMARY OF THE INVENTION

The present invention is directed to a percutaneous gastrostomy device comprising, a tubular portion defining a longitudinal axis, an internal bolster having a radial wing secured to the tubular portion, the internal bolster being flexible to permit elastic deformation between a first orientation generally aligned with the longitudinal axis, with the wing wrapped into a generally cylindrical configuration and a second orientation with the wing unfurled and extending generally transverse to the tubular portion longitudinal axis and a constraining member encasing the internal bolster to retain the internal bolster in the first orientation, with the wing wrapped into the generally cylindrical configuration, and to cover at least a major portion of the wrapped wing, wherein the removal of the casing permits the internal bolster to move from the first orientation to the second orientation.

In accordance with one aspect of this invention, a method and apparatus is provided to constrain a medical device or substance in a dissolvable material and release it inside the body.

In accordance with another aspect of this invention, a novel and improved medical device packaging and delivery method is provided.

In accordance with still another aspect of this invention, the novel and improved medical delivery method has a wide range of applications including, but not limited to, catheters, stents, invasive radiology, etc.

In normal operation of the illustrated embodiment, this invention gives the care giver a positive indication that the device has been released.

These and other aspects of this invention are illustrated in the accompanying drawings, and are more fully disclosed in the following specification.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the gastrostomy feeding device with a capsuled constraining member and ripcord according to one aspect of the present invention;

FIG. 1A is a perspective view of the gastrostomy feeding device according to the present invention deployed and installed in a patient's stomach;

FIG. 2 illustrates a rod member assembly according to the present invention;

FIG. 3 illustrates an internal bolster secured to a tubular portion;

FIG. 3A illustrates the internal bolster secured to a tubular portion and the rod member's distal end received within a pocket of the internal bolster;

FIG. 3B illustrates the internal bolster secured to a tubular portion and the rod member's distal end received within a pocket of the internal bolster and the internal bolster folded around the tubular portion;

FIG. 4 is an exploded view showing the internal bolster and a single loop ripcord deployment method;

FIG. 4A illustrates the internal bolster folded with the rod member installed and with a capsule constraining member and single loop ripcord deployment method;

FIG. 5 illustrates the capsule loading fixtures according to the present invention;

FIG. 6 is an exploded view showing the installation of the ripcord into the capsule and through the assembly fixture according to the present invention;

FIG. 7 illustrates the capsule with ripcord in the assembly fixture according to one aspect of the present invention;

FIG. 8 illustrates an alternate embodiment of the gastrostomy feeding device with a wrapped constraining member;

FIG. 9 illustrates a partial perspective view of an alternate embodiment of the gastrostomy with the rod member outside the tubular portion and with a wrapped constraining member;

FIG. 10 illustrates an exploded view showing the internal bolster and a double loop ripcord deployment method

FIG. 10A illustrates the gastrostomy device folded with the rod member installed and with a capsule constraining member and double loop ripcord deployment method; and

FIG. 11 is an end view of the capsule using the double loop deployment method for the ripcord of the present invention.

DESCRIPTION OF THE INVENTION

With reference to the drawing figures, a gastrostomy device **10** and a method of assembling the device **10** is illustrated. The gastrostomy device **10** with dissolvable capsule and ripcord is illustrated in FIG. 1. As shown in FIG. 1A, once deployed, the gastrostomy device consists of a proximal extension **12** positioned outside the body and a distal extension **14** positioned within the body.

The gastrostomy device **10** is inserted inside the body and positioned on the patient's abdomen by an adjustable silicone locking ring **40**. As shown in FIG. 1 and 1A, the locking ring **40** is provided with a plurality of vent holes **42** and circular ridges **44** to permit air to contact the entry to the body and reduce infection and irritation. Use of the ring **40**, prevents the gastrostomy device **10** from being drawn into the body.

The gastrostomy device **10** includes a tubular portion **16** having a distal end **18** and a proximal end **17**. The distal end **18** has an internal bolster **30** secured thereto. The tubular portion **16** and the internal bolster

30 may be integrally molded together from a bio-compatible material, such as a silicone rubber.

Referring to FIG. 2, rod member **20** comprises a hollow tube **21** having a proximal end **22** and a distal end **24**. The rod member **20** is positioned inside the tubular portion **16** of device **10**, as will be discussed more fully hereinafter. As shown in FIG. 2, the rod member **20** is hollow along its longitudinal axis and includes a handle **25** at its proximal end **22**.

Referring to FIG. 3, an internal bolster **30** has a first part **31** and a second part **33**. The first and second parts **31**, **33** cooperate to provide lateral regions **34**. The lateral regions **34** are secured in a deformed condition when the internal bolster **30** is in an installed configuration.

The first part **31** of the internal bolster **30** is generally semi-oval. The second part **33** of the bolster is integrally connected to the first part and defines a radial wing **35**. The radial wing **35** includes, on its outer surface, a pocket **32** for receipt of the rod member **20** (FIG. 2) to permit deformation of the internal bolster **30** from a first orientation, to a second orientation, as will be discussed more fully hereinafter.

With specific reference to FIG. 3, the tubular portion **16** includes a proximal end **17**, through which food is fed and a distal end **18** that is positioned within the body for insertion in a patient's stoma. The internal bolster **30** is located on the distal end **18** of tubular portion **16**. A pocket **32** for receipt of the proximal end **24** of the rod member **20** (FIG. 2) is also located on the internal bolster **30**.

With specific reference to FIG. 3A, the rod member **20** extends within the tubular portion **16** and includes a projecting end **26** that extends beyond the tubular portion opening **19** at the distal end **18** of the tubular portion. The rod member projecting end **26** is removably inserted into the pocket **32** provided on the radial wing **35**. As shown in FIG. 3A, the radial wing **35** of the internal bolster **30** is bent or deformed by the rod member **20** to be in-line with an axis A of the tubular portion **16**, as illustrated.

As shown in FIG. 3B, the internal bolster **30** is folded around the distal end **18** of the feeding tube **16**, therefore allowing the internal bolster **30** to be inserted inside a capsule as will be discussed more fully hereinafter.

Referring now to FIG.4, a capsule **62** encases the internal bolster to retain the internal bolster **30** in the first orientation, with the wing wrapped into a generally cylindrical configuration and to cover at least a major portion of the wrapped wing. The constraining member may be in the form of a capsule **62.** The capsule **62** is formed into a hollow tubular shape with one open end and one end rounded to a hemispherical shape. On the rounded end of the capsule **62** is located a hole **66** through which a ripcord **50** is threaded as will be described in further detail below. The capsule **62** is located on the distal extension **14** of the gastrostomy device **10.** The capsule **62** is placed over the folded internal bolster **30** as shown in FIG. 4. The capsule **62** maintains the internal bolster

30 in its folded position until the gastrostomy device **10** is deployed inside of the body.

The gastrostomy feeding device **10** as described, employs a ripcord **50**. The ripcord **50,** as shown in FIG. 4A, is provided with a pull tab **52**. The ripcord **50** is threaded through the hollow tube **21**, through the opening **36** in pocket **32** (FIG. 4) on internal bolster **30**, through the passage in the pocket, and out through pocket exit hole **38**, through capsule **62**, through hole **66** in the capsule, along the sidewall of the capsule and back through pocket exit hole **38** and back through hollow tube **21**. Both ends of the ripcord **50** extend through the handle **25** of rod member **20** and are fastened to a pull tab **52**. The pull tab **52** is positioned at the proximal extension **12** of the completed gastrostomy feeding device **10**.

Referring now to FIG. 5, an assembly fixture **70** includes a capsule holder **72** and funnel **74**, employed to assemble a folded internal bolster **30** inside of the capsule **62.** The capsule holder **72** is a rigid cylindrical body containing a cylindrical recess **73** for accommodating an empty capsule **62** and an air pocket relief aperture **75** at the end section **78** of the cylinder recess **73**. The funnel **74** is defined by a conical recess **79** at one end, and cylindrical recess **76** at the other end. During assembly, the capsule **62** (FIG. 7) is placed in the capsule holder **72.** The capsule holder **72** is then fitted into the cylindrical recess **76** of funnel **74**, and the conical shape of conical recess **79** acts as a funnel to guide the internal bolster **30** into the open end of the capsule **62**.

Referring now to FIG. 6, the assembly of the gastrostomy **10** device with the dissolvable capsule **62** and the ripcord **50** will now be described. The rod member **20** is inserted into the end of the tube **16**, and out through the hole in the center of the internal bolster **30** and into the pocket **32**.

A length of ripcord **50** is threaded through a hole **66** (FIG. 4) located in the end of capsule **62**. Both ends of the ripcord **50** are then threaded through the funnel **74** (FIG. 6) of assembly fixture **70**, through pocket **32** on internal bolster **30** (FIG. 4), though the hollow tube **21**, and through the handle **25** and fastened to the pull tab **52**. The capsule **62** and ripcord **50** are then inserted into the assembly fixture **70** as shown in FIG. 7. The sides of the internal bolster **30** are folded by the conical recess **79** as the rod member **20** and ripcord **50** are inserted into the assembly fixture **70** and into the capsule to the position shown in FIG. 7.

The feeding tube assembly, as shown in FIG. 4, is removed from the assembly fixture **70** with the folded internal bolster **30** contained inside the capsule **62** and the ripcord **50** exposed.

The constraining member **60** may also be a wrapping **64** as shown in FIG. 8. The wrapping **64** acts to contain the internal bolster **30** in its folded position in a similar way as is achieved with the capsule **62**. Prior to assembly, the wrapping **64** is in the form of a long narrow strip. The strip of wrapping is manually wrapped about the folded internal bolster **30** to secure it in the folded position for insertion into the body. The wrapping

forms the constraining member **60** around the folded internal bolster **30** in any thickness, shape or manner desired. A ripcord **50** may also be employed with the wrapper in a manner similar to that of the capsule **62** as discussed above as the first embodiment for deployment. The capsule **62** or wrapping **64** may be made of a material such as vegetable cellulose (HPMC). The material is such that upon insertion of the capsule or wrapping inside the body, the capsule **62** or wrapping **64** may dissolve inside the body.

One technique for emplacement of the gastrostomy device **10** is to insert the distal end **14** of the gastrostomy device through the stoma and into the stomach. The constraining member **60** (either the capsule **62** or the wrapping **64**) is released by grasping the handle **25** with one hand and pulling the tab **52** of the ripcord **50** with the other hand. This action tightens up the loop in the ripcord **50** to tear through the sidewall of the constraining member **60**. The projecting member **26** of the rod is withdrawn from the pocket **32** by grasping the proximal extension **12** of the device **10** and pulling the handle **25**. This frees the bolster **30** and the bolster returns to its original shape as illustrated in FIG 1A. The torn member **60** then dissolves inside the body.

Another technique for emplacement of the gastrostomy device **10** is to insert the distal end **14** of the gastrostomy device through the stoma and into the stomach and then the constraining member **60** (either the capsule **62** or the wrapping **64**) is released by the dissolution of the

constraining member by the patient's bodily fluids located inside the patients stomach to free the bolster **30**. The constraining member **60** is made of a material dissolvable in the patient's stomach at a temperature range of between 50 -100 degree F.

Using this technique, the ripcord **50** acts as a deployment indicator, when the ripcord can be withdrawn with little or no resistance, the bolster **30** has returned to its original shape as illustrated in FIG. 1A.

With specific reference to FIG. 9, a partial perspective view of an alternate embodiment of the present invention is shown where the rod member **20** preferably extends alongside and generally parallel to the tubular portion **16** at the distal end **18** of the gastrostomy device **10**. In this alternative embodiment, the constraining member **60** may be either a wrapping **64** or a capsule **62** and will operate as described above in the previous embodiment. In addition, the emplacement technique to free the bolster **30** may be either by the use of a ripcord **50** or from the dissolution of the constraining member **60** by the patient's bodily fluids located inside the patient's stomach as described above in the previous embodiment.

When using the dissolution technique, the time necessary for dissolution of the constraining member **60** may be controlled by injecting a diluent, such as water, through the tube **16**. The diluent travels along axis A (FIG. 3) and into the capsule **62** (FIG. 4), out of the hole **66** and into the patient's stomach (FIG. 1A). Controlling how and when the dissolution

takes place may be achieved in a number of ways, for example, by varying the dissolution temperature of the constraining member, by varying the molecular weight and degree of hydrolysis of the diluent, by varying the rate of diluent delivery, and by varying the amount of exposed surface area used on the constraining member.

With specific reference to FIG. 10, the ripcord is shown using a double loop deployment arrangement. In using the double loop arrangement, the ripcord **50** is laced though the capsule **62** twice. The exposed ripcords are positioned 180 degrees apart (FIG. 11) and when the ripcord **50** is pulled, the capsule is cut into two halves. The emplacement technique to free the bolster **30** in the double loop arrangement may be either by the use of a ripcord **50** or from the dissolution of the constraining member **60** by the patient's bodily fluids. In addition, in the double loop arrangement as shown in FIG. 12, the ripcord **50** can exit the tube **16** through hollow tube **21** of rod member **20** (path I as illustrated in FIG. 12) or through the end of the tube **16** (path O as illustrated in FIG. 12).

In addition as shown in FIG. 12, the ripcord **50** as it loops in either the double loop or single loop arrangement around capsule **62** engages in a slot section **58** that enables the ripcord to tightly fit along the outside of capsule **62**.

Although the invention has been shown and described with respect to a certain embodiment, it is obvious that equivalent alterations and

modifications will occur to others skilled in the art upon reading and understanding of the specification. The present invention includes all such equivalent alterations and modifications, and is limited only by the scope of the claims.